

### **REMARKS**

Applicants have amended the claims to more distinctly point out and claim the present invention. The amendment to claim 37, regarding the use of a high speed mixer to blend, is supported by the specification at page 13, lines 3-8, as well as claim 39. The amendment to claim 37 regarding the lack of any heating, melting, dissolving, or freezing is supported by the entire specification, including for example page 6, lines 8-19, and page 4, line 26 – page 5, line 4. Claims 38, 41, and 43-46 have been amended to depend on claim 37, as these claims depended on a canceled claim. These amendments are supported by their respective underlying claims, and do not introduce new matter. Claim 39 has been incorporated into claim 37, and claim 39 has been cancelled. Claims 19-36 have been canceled, and new claims 47-56 have been added. New claim 47 is supported by claim 20, as well as page 11, lines 7-16 of the specification. New claim 48 is supported by claim 21, as well as page 17, line 9. New claim 49 is supported by claim 22, as well as page 17, lines 9-11. New claim 50 is supported by claim 23, as well as page 12, lines 4-12. New claim 51 is supported by claim 24, as well as page 12, lines 4-19. New claim 52 is supported by claim 25, as well as page 12, lines 12-14. New claim 53 is supported by claim 26, as well as page 12, lines 17-19. New claim 54 is supported by claim 27, as well as page 13, lines 15-20. New claim 55 is supported by claim 28, as well as page 11, lines 7-16. New claim 56 is supported by claim 29, as well as page 14, lines 3-9 and 22-28. New claim 57 is supported by claim 32, page 20, lines 1-12, as well as page 22, lines 7-8. These amendments do not introduce new matter, and their entry is respectfully requested.

The amendment filed January 27, 2004 was objected to under 35 U.S.C. 132, because the Examiner alleged the phrase “in the absence of any solvent” introduced new matter into the

disclosure. While Applicants respectfully disagree, in order to expedite prosecution, the present amendment has removed this language. Accordingly, Applicants respectfully submit that the amendment has obviated this rejection, and respectfully request its withdrawal.

Claims 19-46 were rejected under 35 U.S.C. § 112, first paragraph.

As described above, in order to expedite prosecution, the claims have been amended to remove the recitation “in the absence of any solvent.” Applicants respectfully submit that this amendment has obviated this rejection, and respectfully request its withdrawal.

Accordingly, in view of the foregoing, Applicants respectfully submit that all claims comply with 35 U.S.C. § 112, first paragraph.

Claims 19-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over GB 1,480,175 in light of Kondo et al (U.S. Pat. No. 5,098,907).

Applicants respectfully submit that this rejection should be withdrawn for the following reasons.

As explained in the specification, prior methods to make a fast disintegrating tablet have required complex procedures. In contrast, the present method uses a **high speed mixer** to thoroughly blend an active agent with a surface modifying material, **without heating, melting, dissolving, or freezing** to produce the desired table.

Neither Kondo et al. nor GB 1480175 teach or suggest that one can obtain a tablet by the claimed method for producing a fast disintegrating tablet. The combination also fails to teach or suggest that such a method can produce a surface modified powder which has a flowability of at most 42° in terms of an angle of repose and thus enables direct tableting, and that the surface modified powder is blended with a disintegrant, followed by direct tableting. The fast disintegrating tablet made by the present method has a suitable disintegratability and solubility,

such that when a subject puts the tablet in the mouth, the tablet neither adheres to nor chokes in the throat. Such easily tolerated tablets are particularly desirable for patients such as elderly and pediatric patients.

The superior properties of tablets prepared according to the present method have been well established. The fast disintegrating tablet which is obtained using the instant method has an excellent disintegratability, as described in the specification at page 50, lines 17 to 25 and as demonstrated in Test Examples 1 and 2 of the specification. Applicants have also previously submitted a copy of the inventors' article describing these superior tablets: Kato et al., J. Pharm. Sci. Technol., Jpn. 62:87-94 (2002); see Amendment dated December 29, 2003.

The combination of references cited completely fails to teach or suggest the present method. GB 1480175 teaches that using maltose as the excipient allegedly provides superior properties (see pages 2 and 3 and Figures 1 and 2).

Accordingly, there is nothing in GB 1480175 that teaches or suggests generating a fast disintegrating tablet by using a high speed mixer to thoroughly blend the active agent and a surface modifying material to form a surface modified powder having a flowability with the required angle of repose.

Although the Examiner has alleged that GB 1480175 teaches a composition comprising an active agent, a lubricant, and a disintegrant (see p. 4, ¶ 2 of the Office Action dated November 30, 2004), the Examiner's reading of this reference completely overlooks the requirement of the use of maltose in the GB method. See e.g. column 2, lines 85-90, as well as claim 1.

Kondo in no way teaches the present method. Indeed, the Examiner has implicitly acknowledged this by stating that Kondo is being cited for the teaching of using light anhydrous silicic acid and magnesium stearate to improve the flowability. Kondo in no way teaches using a

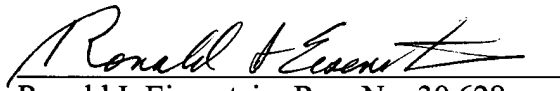
high speed mixer to thoroughly blend an active ingredient with a surface modifying material without heating, melting, dissolving or freezing. Indeed, Kondo shows methods using freezing and dissolving. Accordingly, Kondo et al. teach nothing whatsoever of the claimed method and neither does GB 1480175. Thus, the rejection should be withdrawn

In view of the foregoing, Applicants respectfully submit that all claims comply with 35 U.S.C. §§ 103 and 112 and are in condition for allowance. Early and favorable action is requested.

In the event that any additional fee is required, please charge Deposit Account No. 50-0850.

Respectfully submitted,

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